

Translation

PATENT COOPERATION TREATY

PCT/JP2003/009855



PCT Rec'd PCT/PTO 02 FEB 2005

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | |
|---|--|---|
| Applicant's or agent's file reference 03PCFP885 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/JP2003/009855 | International filing date (day/month/year) 04 August 2003 (04.08.2003) | Priority date (day/month/year) 02 August 2002 (02.08.2002) |
| International Patent Classification (IPC) or national classification and IPC G01N 21/05, 21/77, 21/78, 27/26, 27/49, 21/45, 35/08, 11/00 | | |
| Applicant NEC CORPORATION | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 5 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

| | |
|---|---|
| Date of submission of the demand 04 August 2003 (04.08.2003) | Date of completion of this report 11 January 2005 (11.01.2005) |
| Name and mailing address of the IPEA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/009855

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages _____ 1-52 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages _____ 10-40 _____, as originally filed
 pages _____, as amended (together with any statement under Article 19
 pages _____, filed with the demand
 pages _____ 1-9, 41-43 _____, filed with the letter of _____ 06 September 2004 (06.09.2004)
- ☒ the drawings:
 pages _____ 1/29-29/29 _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

- These elements were available or furnished to this Authority in the following language _____ which is:
- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: I.

The feature added to claim 1, wherein "the areas other than the area to which a channel is provided are made from a transparent material" is not supported by the description at the time of filing, and the amendment is acknowledged to go beyond the scope of disclosure at the time of filing.

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☐ claims Nos. _____

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8-11, 13, 14, 16-19, 23-28, 32-34, 36-43.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

The feature common to claims 1-14, 18, 19, 23, 25-28, 32-34 and 36-43 is elements comprising "a substrate provided with a channel" and "detection part provided at a region of the channel, which induces a change in appearance when a specified substances flows through the channel (upon contact with the specified substance)" (common feature 1). However, as a result of this search, it has become apparent that an analytic apparatus provided with the aforementioned elements is described in JP 2001-337083 A (Sumitomo Electric Industries, Ltd.), 7 December 2001 (07.12.01), all pages and JP 2001-74724 A (Takashi Inaga), 23 March 2001 (23.03.01), entire description, and hence lacks novelty.

Consequently, the aforementioned elements do not go beyond the scope of prior art, and hence this common feature (the aforementioned elements) does not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence.

The other claims 15-17, 20-22, 24, 29-31 and 35 do not involve the aforementioned common feature.

On the other hand, the "lens covering the detection part" which is an element of claim 1 other than those mentioned above is common to claims 1, 5-11, 13, 14, 16-19, 23, 25-28, 32-34 and 36-40 (common feature 2). It has become apparent as a result of this search that this matter is also described in JP 7-500191 A (Sapidyne, Inc.), 5 January 1995, entire description, and hence lacks novelty.

Consequently, this common feature 2 does not go

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

beyond the scope of prior art, and hence does not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence.

Claims 2-4, 12, 15, 20-22, 29-31 and 35 do not involve the aforementioned common feature 2.

Further, all the elements of claim 1, namely, "a substrate provided with a channel", "a detection part disposed at a region of the channel, which induces appearance change when a specified substance flows through the channel (upon contact with the specified substance)" and "a lens covering the detection part" (common feature 3) are common to claims 1, 5-11, 13, 14, 16-19, 23, 25-28, 32-34 and 36-43. However, it has become apparent as a result of search that this matter is also described in JP 7-500191 A (Sapidyne, Inc.), 5 January 1995, entire description, and hence lacks novelty.

Consequently, the aforementioned common feature 3 does not go beyond the scope of prior art, and hence it does not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence.

Claims 2-4, 12, 15, 20-22, 29-31 and 35 do not involve the aforementioned common feature 3.

In summing up, there is no feature common to all of the claims.

Since there is no other common feature which may be considered as a special technical feature within the

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV. 3.

meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 can be found between these different inventions.

When claim 1 is regarded as the first claim, the technical feature as a difference from the aforementioned "common feature 1" which lacks novelty are "a lens covering the detection part" and "the part other than the part where a channel is provided is made from a transparent material" but the claims apart from claims 5-11, 13, 14, 16-19, 23, 25-28, 32-34, 36-43 which are all dependent on claim 1, do not share a common technical feature. That is to say, independent claims 2, 3, 4, 12, 15, 20, 21, 22, 24, 29, 30 and 35 do not contain the same common feature as claim 1, and therefore constitute a different group of inventions.

Therefore, besides claims 1, this application contains twelve (12) other inventions.

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VI. Certain documents cited

1. Certain published documents (Rule 70.10)

| <u>Application No. Patent No.</u> | <u>Publication date (day/month/year)</u> | <u>Filing date (day/month/year)</u> | <u>Priority date (valid claim) (day/month/year)</u> |
|---------------------------------------|--|---|---|
| JP 2003-247932 A (EX) | 05 September 2003 (05.09.2003) | 26 February 2002 (26.02.2002) | |
| JP 2002-277478 A (EX) | 25 September 2002 (25.09.2002) | 15 March 2001 (15.03.2001) | |
| JP 2003-156474 A (EX) | 30 May 2003 (30.05.2003) | 20 November 2001 (20.11.2001) | |

2. Non-written disclosures (Rule 70.9)

| <u>Kind of non-written disclosure</u> | <u>Date of non-written disclosure (day/month/year)</u> | <u>Date of written disclosure referring to non-written disclosure (day/month/year)</u> |
|---------------------------------------|--|--|
| | | |

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | | |
|-------------------------------|--------|---|-----|
| Novelty (N) | Claims | | YES |
| | Claims | 1 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1 | NO |
| Industrial applicability (IA) | Claims | 1 | YES |
| | Claims | | NO |

2. Citations and explanations

Document 1: JP 7-500191 A (Sapidyne, Inc.), 5 January 1995

The invention set forth in claim 1 lacks novelty and does not involve an inventive step in the light of document 1.

Document 1 sets forth an analysis chip comprising a substrate (50) having a channel, detection portions (38, 40) which generate fluorescent light when ligands flow through said channel, and a channel covering member (30) which is integrally formed with the lens which covers said channel, and there is no difference between the configuration of this invention and the invention set forth in claims 1 and 2.

Therefore claim 1 lacks novelty in the light of document 1.

For the reasons set forth in Box I.5, the aforementioned assessment of novelty and inventive step was carried out based on the part of the disclosure corresponding to claim 1 at the time of filing, excluding the parts added with the correction dated 6 September 2004.